PCT/DK00/00040

AMENDED SET OF CLAIMS

REPLY TO FIRST WRITTEN OPINION 27 APRIL 2001

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1. A device for determining one or more respiratory parameters relating to an individual, comprising

a gas flow device having means for conducting a flow of inspiratory gas from an inlet opening to the respiratory system of the individual and a flow of expiratory gas from the respiratory system of the individual to an outlet opening,

a gas-mixing unit for supplying a substantially homogeneous gas to the inlet opening of the gas flow device,

first supply means for supplying a first gas to an inlet of the gas mixing unit and having first control means for controlling the flow of the first gas,

second supply means for supplying a second gas having an oxygen fraction different to the gas supplied from the first supply means to an inlet of the gas mixing unit and having second control means for controlling the flow of the second gas,

a computer for determining said one or more respiratory parameters,

first detection means for detecting the level of oxygen (SaO_2, SpO_2, PaO_2, PpO_2) in the blood circulation of the individual and producing an output to the computer accordingly, and

second detection means for detecting the level of oxygen (FIO_2, $FE'O_2$, $F\bar{E}O_2$, PIO_2, $PE'O_2$, $P\bar{E}O_2$) in the gas flow passing into or out of the respiratory system of the individual and producing an output to the computer accordingly,

the computer being adapted for retrieving and storing at least two measurements being the concurrent output produced by the first detection means and the second detection means within a data structure, in which the two stored outputs are mutually related, in data storage means associated with the computer, the at least two measurements being conducted at respective levels of oxygen in the gas flow passing into the respiratory system, the computer further being adapted for determining at least two respiratory parameter (Rdiff, shunt, $\dot{V}/\dot{Q}$, H-shift, V-shift) being descriptive of the pulmonary gas exchange of the individual, the determination being based on the at least two measurements.

2. A device according to claim 1, wherein said parameter(s) (Rdiff, shunt, $\dot{V}/\dot{Q}$, H-shift, V-shift) is/are generalised parameters being comparable to similar parameter(s) determined for other individuals.

3. A device according to claim 1 or 2, wherein the computer further is adapted for performing a procedure at least once, the procedure comprising

determining, based on at least two measurements, whether additional measurements are required,

asserting a possible desired target defining a desired output of the first detection means,

producing a possible control data item based on the target, and

retrieving and storing, in the data structure, additional measurement results being the concurrent output produced by the first detection means and the second detection means.

4. A device according to any of claims 1-3, wherein the second detection means are arranged for detecting the level (FIO2, PIO2) of oxygen in the gas flow passing into the respiratory system, and the device further comprises

third detection means for detecting the level (FE'O2, FĒO2, PE'O2, PĒO2) of oxygen in the gas flow passing out of the respiratory system and producing an output to the computer accordingly, and

fourth detection means for detecting variables (Vt, f, $\dot{V}$) of the gas flow passing the respiratory system and producing an output to the computer accordingly, said output being sufficient for the computer to establish the volume flow of gas passing the respiratory system,

the computer being adapted for retrieving and storing output from the third detection means and the fourth detection means within the data structure relating these stored output mutually as well as with the output from the first detection means and the second detection means retrieved simultaneously.

5. A device according to claim 4, wherein the computer further being adapted for establishing, based on said measurement(s), the oxygen consumption (VO2) of the individual.

6. A. device according to any of claims 1-5, wherein the computer is adapted to determine a parameter relating to an equilibrium state of the overall oxygen uptake or consumption of the individual based on the output of at least one of the detection means, to compare said parameter with a predefined threshold value and to produce a control data item accordingly if said parameter exceeds said threshold value.

7. A device according to any of claim 1-6, wherein the computer is adapted to asses the appropriate change in oxygen level in the inspired gas (FIO2) from the current oxygen level (FIO2) so as to achieve a given desired target oxygen level in the blood (SaO2, SpO2, PaO2, PpO2) and produce a control data item accordingly.

8. A device according to claim 7, wherein the assessment of change in oxygen level in the inspired gas is based on a predefined set of data representing statistical distributions of parameters stored within data storage means associated with the computer and on said measurements.

9. A device according to claim 7, wherein the assessment of change in oxygen level in the inspired gas is based on the rate of change of the output of at least one of the detection means in response to a change in oxygen level (FIO2) in the inspired gas flow.

10. A device according to any of claims 7-9, wherein the computer is adapted to operate the control means for controlling the flow to the gas mixing unit of at least one gas, in response to said control data item relating to the assessed change in oxygen level from the computer so as to change the oxygen level (FIO2) in the inspired gas flow accordingly.

11. A device according to any of claims 1-10, wherein one gas is atmospheric air and another gas has an oxygen fraction higher than that of atmospheric air, preferably in the range 0.85 to 1.00.

12. A device according to any of claims 1-11, wherein one gas is atmospheric air and another gas has an oxygen fraction in the range of 0.00 to 0.21, preferably 0.00 to 0.05.

13. A device according to any of the preceding claims, wherein the oxygen saturation in the blood circulation of the individual is in the range of 65 to 100%, preferably 85 to 100%.

14. A device according to any of claims 1-13, wherein the first detection means is arranged for detecting a parameter relating to the saturation level of oxygen in the arterial blood stream.

15. A device for determining one or more respiratory parameters relating to an individual, comprising

a gas flow device having means for conducting a flow of inspiratory gas from an inlet opening to the respiratory system of the individual and a flow of expiratory gas from the respiratory system of the individual to an outlet opening,

a gas-mixing unit for supplying a substantially homogeneous gas to the inlet opening of the gas flow device,

first supply means for supplying a first gas to an inlet of the gas mixing unit and having first control means for controlling the flow of the first gas,

second supply means for supplying a second gas having an oxygen fraction different to the gas supplied from the first supply means to an inlet of the gas mixing unit and having second control means for controlling the flow of the second gas,

a computer for determining said one or more respiratory parameters,

first detection means for detecting the level of oxygen (SaO_2, SpO_2, PaO_2, PpO_2) in the blood circulation of the individual and producing an output to the computer accordingly, and

second detection means for detecting the level of oxygen (FIO_2, $FE'O_2$, $F\bar{E}O_2$, PIO_2, $PE'O_2$, $P\bar{E}O_2$) in the gas flow passing into or out of the respiratory system of the individual and producing an output to the computer accordingly,

the computer being adapted for retrieving and storing a first measurement being the concurrent output produced by the first detection means and the second detection means within a data structure, in which the two stored outputs are mutually related, in data storage means associated with the computer, the computer being further adapted for performing a procedure at least once, the procedure comprising

determining, based on data stored within the data structure, whether additional measurements are required,

asserting a possible desired target defining a desired output of the first detection means,

producing a possible control data item based on the target, and

retrieving and storing, in the data structure, additional measurement results being the concurrent output produced by the first detection means and the second detection means.

16. A device according to claim 15, wherein the second detection means are arranged for detecting the level (FIO2, PIO2) of oxygen in the gas flow passing into the respiratory system, and the device further comprises

third detection means for detecting the level (FE'O2, FĒO2, PE'O2, PĒO2) of oxygen in the gas flow passing out of the respiratory system and producing an output to the computer accordingly, and

fourth detection means for detecting variables (Vt, f, $\dot{V}$) of the gas flow passing the respiratory system and producing an output to the computer accordingly, said output being sufficient for the computer to establish the volume flow of gas passing the respiratory system,

the computer being adapted for retrieving and storing output from the third detection means and the fourth detection means within the data structure in data storage means associated with the computer, in which the stored outputs are mutually related and related to the output from the first detection means and the second detection means, and the output from the four detection means can be retrieved simultaneously.

17. A device according to claim 16, wherein the computer further being adapted for establishing, based on said measurement(s), the oxygen consumption (VO2) of the individual.

18. A device according to claim 15 or 16, wherein the computer is adapted for determining at least one respiratory parameter (Rdiff, shunt, $\dot{V}/\dot{Q}$, H-shift, V-shift) being descriptive of the condition of the individual, the determination being based on at least two measurements.

19. A device according to claim 18, wherein at least two respiratory parameters (Rdiff, shunt, $\dot{V}/\dot{Q}$, H-shift, V-shift) are determined.

20. A device according to claim 18 or 19, wherein said parameter(s) (Rdiff, shunt, $\dot{V}/\dot{Q}$, H-shift, V-shift) is/are generalised parameters being comparable to similar parameter(s) determined for other individuals.

21. A. device according to any of claims 15-20, wherein the computer is adapted to determine a parameter relating to an equilibrium state of the overall oxygen uptake or consumption of the individual based on the output of at least one of the detection means, to compare said parameter with a predefined threshold value and to produce a control data item accordingly if said parameter exceeds said threshold value.

22. A device according to any of claims 15-21, wherein the computer is adapted to asses the appropriate change in oxygen level in the inspired gas (FIO2) from the current oxygen level (FIO2) so as to achieve a given desired target oxygen level in the blood (SaO2, SpO2, PaO2, PpO2) and produce a control data item accordingly.

23. A device according to claim 22, wherein the assessment of change in oxygen level in the inspired gas is based on a predefined set of data representing statistical distributions of parameters stored within data storage means associated with the computer and on said measurement(s).

24. A device according to claim 22, wherein the assessment of change in oxygen level in the inspired gas is based on the rate of change of the output of at least one of the detection means in response to a change in oxygen level (FIO2) in the inspired gas flow.

25. A device according to any of claims 22-24, wherein the computer is adapted to operate the control means for controlling the flow to the gas mixing unit of at least one gas, in response to said control data item relating to the assessed change in oxygen level from the computer so as to change the oxygen level (FIO2) in the inspired gas flow accordingly.

26. A device according to any of claims 15-25, wherein one gas is atmospheric air and another gas has an oxygen fraction higher than that of atmospheric air, preferably in the range 0.85 to 1.00.

27. A device according to any of claims 15-26, wherein one gas is atmospheric air and another gas has an oxygen fraction in the range of 0.00 to 0.21, preferably 0.00 to 0.05.

28. A device according to any of claims 15-28, wherein the oxygen saturation in the blood circulation of the individual is in the range of 65 to 100%, preferably 85 to 100%.

29. A device according to any of claims 15-28, wherein the first detection means is arranged for detecting a parameter relating to the saturation level of oxygen in the arterial blood stream.

30. A device for determining one or more respiratory parameters relating to an individual, comprising

a gas flow device having means for conducting a flow of inspiratory gas from an inlet opening to the respiratory system of the individual and a flow of expiratory gas from the respiratory system of the individual to an outlet opening,

a gas-mixing unit for supplying a substantially homogeneous gas to the inlet opening of the gas flow device,

first supply means for supplying a first gas to an inlet of the gas mixing unit and having first control means for controlling the flow of the first gas,

second supply means for supplying a second gas having an oxygen fraction different to the gas supplied from the first supply means to an inlet of the gas mixing unit and having second control means for controlling the flow of the second gas,

a computer for determining said one or more respiratory parameters,

first detection means for detecting the level of oxygen (SaO_2, SpO_2, PaO_2, PpO_2) in the blood circulation of the individual and producing an output to the computer accordingly, and

second detection means for detecting the level of oxygen (FIO_2, $FE'O_2$, $F\bar{E}O_2$, PIO_2, $PE'O_2$, $F\bar{E}O_2$) in the gas flow passing into or out of the respiratory system of the individual and producing an output to the computer accordingly,

the computer being adapted for retrieving and storing at least a first measurement being the concurrent output produced by the first detection means and the second detection means within a data structure, in which the two stored outputs are mutually related, in data storage means associated with the computer, the computer further being adapted to asses the appropriate change in oxygen level in the inspired gas (FIO_2) from

the current oxygen level (FIO2) so as to achieve a given desired target oxygen level in the blood (SaO2, SpO2, PaO2, PpO2) and produce a control data item accordingly.

31. A device according to claim 30, wherein the assessment of change in oxygen level in the inspired gas is based on a predefined set of data representing statistical distributions of parameters stored within data storage means associated with the computer and on said measurement(s).

32. A device according to claim 30, wherein the assessment of change in oxygen level in the inspired gas is based on the rate of change of the output of at least one of the detection means in response to a change in oxygen level (FIO2) in the inspired gas flow.

33. A device according to any of claims 30-32, wherein the computer is adapted to operate the control means for controlling the flow to the gas mixing unit of at least one gas, in response to said control data item from the computer so as to change the oxygen level (FIO2) in the inspired gas flow accordingly.

34. A device according to any of claims 30-33, wherein the computer further is adapted for performing a procedure at least once, the procedure comprising

determining, based on at least one measurement, whether additional measurements are required,

asserting a possible desired target defining a desired output of the first detection means,

producing a possible control data item based on the target, and

retrieving and storing, in the data structure, additional measurement results being the concurrent output produced by the first detection means and the second detection means.

35. A device according to any of claims 30-34, wherein the second detection means are arranged for detecting the level (FIO2, PIO2) of oxygen in the gas flow passing into the respiratory system, and the device further comprises

third detection means for detecting the level (FE'O2, FĒO2, PE'O2, PĒO2) of oxygen in the gas flow passing out of the respiratory system and producing an output to the computer accordingly, and

fourth detection means for detecting variables (Vt, f, $\dot{V}$) of the gas flow passing the respiratory system and producing an output to the computer accordingly, said output being sufficient for the computer to establish the volume flow of gas passing the respiratory system,

the computer being adapted for retrieving and storing output from the third detection means and the fourth detection means within the data structure relating these stored output mutually as well as with the output from the first detection means and the second detection means retrieved simultaneously.

36. A device according to claim 35, wherein the computer further being adapted for establishing, based on said measurement(s), the oxygen consumption (VO2) of the individual.

37. A device according to any of claims 30-36, wherein the computer is adapted for determining at least one respiratory parameter (Rdiff, shunt, $\dot{V}/\dot{Q}$, H-shift, V-shift) being descriptive of the condition of the individual, the determination being based on at least two measurements.

38. A device according to claim 37, wherein at least two respiratory parameters (Rdiff, shunt, $\dot{V}/\dot{Q}$, H-shift, V-shift) are determined.

39. A device according to claim 37 or 38, wherein said parameter(s) (Rdiff, shunt, $\dot{V}/\dot{Q}$, H-shift, V-shift) is/are generalised parameters being comparable to similar parameter(s) determined for other individuals.

40. A. device according to any of claims 30-39, wherein the computer is adapted to determine a parameter relating to an equilibrium state of the overall oxygen uptake or consumption of the individual based on the output of at least one of the detection means, to compare said parameter with a predefined threshold value and to produce a control data item accordingly if said parameter exceeds said threshold value.

41. A device according to any of claims 30-40, wherein one gas is atmospheric air and another gas has an oxygen fraction higher than that of atmospheric air, preferably in the range 0.85 to 1.00.

42. A device according to any of claims 30-41, wherein one gas is atmospheric air and another gas has an oxygen fraction in the range of 0.00 to 0.21, preferably 0.00 to 0.05.

43. A device according to any of claims 30-42, wherein the oxygen saturation in the blood circulation of the individual is in the range of 65 to 100%, preferably 85 to 100%.

44. A device according to any of claims 30-42, wherein the first detection means is arranged for detecting a parameter relating to the saturation level of oxygen in the arterial blood stream.

45. Method for determining one or more respiratory parameters by means of a device according to any of the preceding claims, wherein the individual is an apparently healthy individual.

46. Method for determining one or more respiratory parameters by means of a device according to any of the preceding claims, wherein the individual is considered to have a risk of suffering from hypoxemia.

47. Method for determining one or more respiratory parameters by means of a device according to any of the preceding claims, wherein the individual is suffering from hypoxemia.

48. Method according to claim 47, wherein the individual is suffering from one or more disease(s) selected from the group(s) comprising left sided heart failure, adult respiratory distress syndrome, pneumonia, postoperative hypoxemia, pulmonary fibrosis, toxic pulmonary lymphoedema, pulmonary embolisms, chronic obstructive pulmonary disease and cardiac shunting.

49. A computer system comprising at least one general purpose computer having one or more computer programs stored within data storage means associated therewith, the computer system being arranged for as well as being adapted for determining one or more respiratory parameters according to any of claims 1-48.

50. A computer program product being adapted to enable a computer system comprising at least one general purpose computer having data storage means associated therewith and being arranged suitably to determine one or more respiratory parameters according to any of claims 1-48.